1/5/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District

749

1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: (510) 337-6700
FAX: (510) 337-6702

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 4, 1997

Inspection ID: **2103020001**
FDA Reference #: 2952781

Mr. Greg Stupak
Radiology Administrator
NorthBay Healthcare
1010 Nut Tree Road
Vacaville, CA 95687

WARNING LETTER

Dear Mr. Stupak:

Your facility was inspected on November 12, 1997, by Mr. Edward Gloor, a representative from the State of California under contract with the Food and Drug Administration. This inspection revealed that your facility failed to comply with the quality standards for Mammography Quality Standards Act (MQSA) as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. Records indicate that there was no medical physicist survey done for the x-ray system: Mammography.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 and regulations under the Act. The specific violation noted in this letter and in the printed summary of test results and inspection observations issued at the close of the inspection may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be deviations from the quality standards, you must promptly initiate permanent corrective actions.

Failure to take prompt action to correct deficiencies may result in regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil money penalties up to $10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may

also have its certificate suspended or revoked for failure to comply with the Standards. Continuation of any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

You should be advised that FDA regulations do not prevent enforcement of requirements under State laws and regulations. In some cases, State requirements may be more stringent than requirements under FDA regulations. You may receive a letter or notification from the State advising you of this fact. When conducting corrective action, you should take into consideration the more stringent requirements. A copy of your response to the FDA should always be sent to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. In your response, you must also respond to the items on your printout. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If your response includes equipment test results, please include equipment settings (including technique factors), raw test data, and calculated final results, where appropriate. If the noncompliances found relate to quality control or other records, example records showing compliant recordkeeping should be included with your submission (patient names or identification should be omitted from any copies submitted).

Your response should be sent to:

Mr. John M. Doucette
MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

Sincerely yours,

Patricia C Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: Trisha Edgerton, Chief, Mammography Accreditation
Edward Gloor, MQSA Inspector (2009)
California Department of Health Services
Radiological Health Branch
P.O. Box 942732
601 N. 7th Street
Sacramento, CA 94234-7320